Nasal Expiratory Positive Airway Pressure (Provent®)
Criteria for Use

VA Pharmacy Benefits Management Services, Medical Advisory Panel and VISN Pharmacist Executives

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. **THE CLINICIAN SHOULD UTILIZE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.**

The Product Information should be consulted for detailed prescribing information.

Exclusion Criteria *If the answer to ANY item below is met, then the patient should NOT receive Provent Therapy.*

- ❑ Complex Sleep Apnea
- ❑ Central Sleep Apnea
- ❑ Snoring without a diagnosis of Obstructive Sleep Apnea
- ❑ Severe breathing disorder (including respiratory muscle weakness, bullous lung disease, bypassed upper airway, pneumothorax, pneumomediastinum, etc)
- ❑ Severe heart disease (including heart failure) SEE ISSUES FOR CONSIDERATION
- ❑ Pathologically low blood pressure
- ❑ An acute upper respiratory (including nasal, sinus or middle ear) inflammation or infection or perforation of the ear drum
- ❑ Sores, abrasions, or skin or mucosal irritation on or around the nose that would preclude use

Inclusion Criteria *All of the following criteria must be fulfilled for prescription benefit coverage.*

- ❑ Mild to Moderate Obstructive Sleep Apnea diagnosed by prior polysomnography (apnea-hypopnea index 5-30)*
- ❑ Intolerance to or unable to use CPAP (valid reason must be established and documented in the patient medical record). Examples include but are not limited to: skin breakdown, interface-related pain or discomfort after use of multiple masks or straps; allergic reaction to mask material, claustrophobia when using CPAP mask; persistent mask leak despite multiple interfaces (e.g., excessive facial hair, shape of face); transient sleeping arrangement; unreliable source of electricity.**
- ❑ Intolerance to CPAP demonstrated by failing a 3 month trial with CPAP unless waiting 3 months is inappropriate (e.g., those with extreme claustrophobia, etc.)
- ❑ Requesting provider is a VA Pulmonary/Sleep specialist, other clinicians with credentials in sleep medicine, or locally designated expert
- ❑ Patient's baseline daytime sleepiness has been documented using Epworth Sleepiness Scale (ESS). See Appendix

**Use of Provent in patients with severe OSA, while not recommended, may be adjudicated locally. Due to severity of the disease and potential serious consequences on health, intensive efforts should be made to address any problems and encourage appropriate use of CPAP (gold standard of treatment) before considering Provent.*

***Use of Provent in patients who refuse or are non-adherent to CPAP may be adjudicated locally*

Dosage and Administration

- Apply one Provent Therapy disc to each nostril at bedtime and remove upon awakening the next morning.
- The first fill is a 30 night treatment pack with starter kit including an instructional CD.
- The second fill is a 90 night treatment pack with 1 refill.

Renewal Criteria

- Pulmonary/sleep follow-up within 3-6 months after starter kit issued.
- Documented adherence by refill history.
- Documented benefit and tolerability (e.g., reassess ESS for daytime sleepiness, snoring, etc. if these were present before starting Provent). See Appendix for average changes in ESS reported in the Provent clinical trials.
- If available, in-lab polysomnogram or portable monitoring is encouraged to determine if patient is receiving adequate treatment response.

Monitoring

- There is no effective means of monitoring adherence to therapy such as there is with CPAP.

Issues for Consideration

- CPAP is the gold standard treatment for Obstructive Sleep Apnea. Poor adherence to CPAP is common; early intervention using strategies to improve adherence to CPAP is encouraged.
- Provent Therapy will not be the primary treatment for Obstructive Sleep Apnea.
- The instructional CD should be sufficient training for most patients but for those requiring more training or who have no means of using the instructional CD a Respiratory Therapy Consult should be requested.
- Severe heart disease is a contraindication to using Provent. Severe heart disease is not defined in the package insert; therefore, cardiac reasons for patient exclusion from the randomized, controlled trial for Provent are provided as examples:
    - NYHA III/IV HF, CAD with angina or MI or stroke in past 6 months, cardiac rhythm disturbance (5-beat run of VT, bradycardia if < 30bpm for 10 sec run, untreated atrial fibrillation or Mobitz II or 3rd degree heart block), uncontrolled HTN (SBP > 180mmHg or DBP > 105mmHg), uncontrolled hypotension (SBP <80mmHg or DBP < 55mmHg)
- Avoid Provent in patients with nasal and sinus problems or who are obligatory mouth breathers secondary to nasal pathology (e.g., septal deviation); significant hypoxia; non-apneic desaturation.

Appendix: Epworth Sleepiness Scale (ESS)

Johns MW. A new method for measuring daytime sleepiness: the Epworth sleepiness scale. Sleep 1991; 14:540-5.

How likely are you to doze off or fall asleep in the following situations, in contrast to feeling just tired? This refers to your usual way of life in recent times. Even if you have not done some of these things recently, try to work out how they would have affected you. Use the following table to mark the *most appropriate number* for each situation:

	0 would *never* doze	1 *slight* chance of dozing	2 *moderate* chance of dozing	3 *high* chance of dozing
Sitting and reading				
Watching TV				
Sitting, inactive in a public place (e.g., a theater or a meeting)				
As a passenger in a car for an hour without a break				
Lying down to rest in the afternoon when circumstances permit				
Sitting and talking to someone				
Sitting quietly after a lunch without alcohol				
In a car, while stopped for a few minutes in traffic				
Total of each number:				

TOTAL SCORE (add all numbers together):_____

Interpretation:
0-7: unlikely patient is abnormally sleepy
8-9: patient has an average amount of daytime sleepiness
10-15: patient may be excessively sleepy depending on the situation and should consider seeking medical attention
16-24: patient has excessive sleepiness and should seek medical attention

Mean changes in ESS reported in studies

Study	Mean Baseline ESS	Mean ESS After Treatment
Berry R, et al. SLEEP 2011	9.9 ± 4.7	7.2 ± 4.2 at 3 months
Kryger M, et al. J Clin Sleep Med 2011	11.1 ± 4.2	6 ± 3.2 at 12 months
Walsh J, et al. Sleep Medicine 2011	12.3 ± 4.8	8.7 ± 4.4 at 5 weeks
Rosenthal L, et al. J Clin Sleep Med.2009	8.7 ± 4	6.9 ± 4.4 at 30 days

Changes in ESS were statistically significant